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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,997	06/11/2004	Mark A. Johanson	22956-302 (MIT-169CON)	3996
21125 7590 01/10/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			NOTIFICATION DATE 01/10/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/709,997

Applicant(s)

JOHANSON ET AL.

Examiner

Julian W. Woo

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 14, 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Simon (5,346,497). Simon discloses, at least in figures 3-13, an apparatus including a tube with an inner bore (3), a distal end having a cutting edge, and at least one recess (6) adjacent the distal end that extends at least part way from the an inner surface of the tube to an outer surface of the tube; and a sheath (2) disposed around the tube and including a tooth (18) extending towards the inner bore in a direction substantially orthogonal to the cutting edge. Note: The introductory statement of intended use ("for harvesting bone plugs from bone tissue") has been carefully considered but deemed not

to impose any structural limitations on the claims patentably distinguishable over Simon's device, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2, 6, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (5,346,497) in view of Stavropoulos et al. (4,142,517). Simon (5,346,497) discloses the invention substantially as claimed, but does not disclose a sheath including one or more markings on an outer surface thereof, the one or more markings corresponding to an amount that the sheath is inserted into bone tissue. Simon also does not disclose that the tube has a handle, nor does Simon disclose that the tube has a mating element at its proximal end, and that the sheath includes a connector for

removable engagement with the mating element. Stavropoulos et al. teach, at least in figures 5 and 6 and in col. 1, line 7 to col. 2, line 51; a sheath (18) mated to a tubular apparatus (40) for harvesting bone plugs, where the sheath includes markings (22) corresponding to an amount that the sheath is inserted into bone tissue. Stavropoulos et al. also teach a tube (40) with a handle (54) and a mating element (46) and a sheath (18) with a connector (46) for removable engagement with the mating element. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Stavropoulos et al., to include a sheath with markings in the device of Simon. Such a sheath would allow a measurement of and a limit to the depth of insertion the tube within a patient's body, and would thus safety prevent overextension of the tube into the patient's body. It would also be obvious to include a handle and a mating element in the tube of Simon and a connector with the sheath of Simon. A handle would allow the rotation of the tube manually or by a motor; while a mating element and a connector would allow the depth of tube penetration into tissue to be measured and controlled.

6. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable Simon (5,346,497) in view of Hallac (3,605,721). Simon discloses the invention substantially as claimed, but does not disclose a tube with at least one recess or aperture beginning a predetermined distance away from the distal end of the tube. Hallac teaches, at least in figures 4, 5, and 8 and in col. 4, lines 25-36; an apparatus for harvesting tissue plugs, where the apparatus includes a tube with cutting edges and a plurality of recesses or apertures (e.g., 52 or 54) each extending from an inner surface of the tube to an outer

surface of the tube and running towards the proximal end of the tube and beginning a predetermined distance away from the distal end of the tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Hallac, to modify the tube in the apparatus of Simon, so that it has a plurality of recesses or apertures adjacent the distal end of the tube. Such recesses or apertures would allow the capturing of tissue to the depth of penetration of the tube within the tissue.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (5,346,497) in view of Torrie et al. (6,358,253). Simon discloses the invention substantially as claimed. Simon discloses an apparatus for harvesting tissue, but does not disclose an apparatus including a bone plug formed from articular cartilage and underlying bone tissue. Torrie et al. teach, at least in col. 7, line 39 to col. 8, line 21, an apparatus including a harvested bone plug (87) formed from articular cartilage (86) and underlying bone tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Torrie et al., to include a bone plug formed from articular cartilage and underlying bone tissue with the apparatus of Simon. Such a bone plug would allow the repair and replacement of bone that is covered with damaged cartilage.

Response to Amendment

8. Applicant's arguments with respect to claims 1-7 and 28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

January 6, 2008